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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CRABTREE, JOSHUA DAVID	
ART UNIT	PAPER NUMBER
3715	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,998	HATLESTAD ET AL.	
	Examiner	Art Unit	
	Joshua D. Crabtree	3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/15/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 35-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In response to the amendment dated 5/12/2006; claims 15-34 and 57-96 cancelled; claims 1-14 and 35-56 pending.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 35-56 are rejected under 35 U.S.C. 101 as being directed toward non-statutory subject matter. In order for a claimed invention to be patentable, it must produce a "useful, concrete and tangible result" (see *State Street,* 149 F.3d at 1373, 47 USPQ2d at 1601-02.) Specifically, claims 1-4 are directed toward an end result of collecting data. The collection of data is an abstraction, and therefore is not tangible. Merely transmitting the data does not render the data tangible. Similarly, claims 35-56 are directed toward an end result of assessing or evaluating sleep quality of a patient. An assessment is an abstraction, and therefore is not tangible. An evaluation is an abstraction, and therefore is not tangible.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 5, 9-14, and 35-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Cho et al. (US 6,641,542).

With regard to claim 1, Cho et al. disclose detecting physiological conditions associated with sleep quality (Col. 4: 29-33). With regard to detecting non-physiological conditions, Cho et al. disclose measuring the sleep time of the patient (Col. 9: 9-19).

With regard to the limitation of collecting sleep quality data based on the detected conditions, using an implantable device, Cho et al. disclose this feature (Col. 5: 5-25).

With regard to claim 2, and the limitation of detecting a cardiovascular condition, Cho et al. disclose detecting hypertension (Col. 4: 53-65).

With regard to claim 3, Cho et al. disclose detecting respiratory conditions, such as Cheyne-Stokes respiration (Col. 6: 61-65).

With regard to claim 5, and the limitation of detecting a blood chemistry condition, Cho et al. disclose detecting oxygen saturation in the blood (Col. 8: 3-20).

With regard to claims 9 and 37, and the limitation of collecting data associated with sleep stages, Cho et al. disclose measuring sleep cycle length (Col. 3: 14-17), and measuring eye movement to determine if the patient has reached the REM stage of sleep (Col. 2: 21-23).

With regard to claims 10 and 38, and the limitation of collecting data associated with sleep disruption, Cho et al. disclose detecting abnormal arouses (Col. 6: 57-65).

With regard to claims 11 and 39, and the limitation of collecting data associated with disordered breathing, Cho et al. disclose detecting apneas and hypopneas (Col. 8: 46-60).

With regard to claims 12 and 40, and the limitation of collecting data associated with a movement disorder, Cho et al. disclose measuring limb movements (Col. 6: 53-65).

With regard to claim 13, and the limitation of storing the collected sleep quality data, Cho et al. disclose storing the data (Col. 5: 35-38).

With regard to claim 14, and the limitation of transmitting the collected sleep quality data, Cho et al. disclose that the data may be transmitted (Col. 8: 38-45).

With regard to claim 35, Cho et al. disclose detecting physiological conditions associated with sleep quality (Col. 4: 29-33). With regard to detecting non-physiological conditions, Cho et al. disclose measuring the sleep time of the patient (Col. 9: 9-19). With regard to the limitation of collecting sleep quality data based on the detected conditions, wherein at least one of collecting and evaluating the sleep quality is performed implantably, Cho et al. disclose this feature (Col. 5: 5-25).

With regard to claim 36, and the limitation wherein the collecting and evaluating of sleep data are performed at least in part implantably, Cho et al. disclose that the

evaluation can be performed by the processor, which is part of the implantable device (Col. 9: 56-60).

With regard to claim 41, and the limitation wherein evaluating the sleep quality comprises determining one or more metrics associated with sleep quality, Cho et al. disclose gathering metrics associated with sleep apnea (Col. 3-24-38).

With regard to claim 42, and the limitation wherein evaluating the sleep quality comprises trending one or more metrics associated with sleep quality over time, Cho et al. disclose determining the number of apneas experienced per hour (Col. 8: 46-60).

With regard to claim 43, and the limitation wherein evaluating sleep quality comprises determining one or more metrics associated with disordered breathing, Cho et al. disclose measuring breathing cycles (Col. 3: 13-23).

With regard to claim 44, and the limitation wherein evaluating sleep quality comprises determining one or more metrics associated with movement disorders, Cho et al. disclose measuring limb movements (Col. 6: 52-65).

With regard to claim 45, and the limitation wherein evaluating sleep quality comprises determining one or more composite metrics based on metrics associated with sleep and metrics associated with events that disrupt sleep, Cho et al. disclose that a combination of factors is used to determine whether a patient has sleep apnea (Col. 2: 18-29; Col. 9: 9-20). .

With regard to claim 46, Cho et al. disclose transmitting sleep quality data and the sleep quality evaluation to a separate device (Col. 8: 39-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 4, and 47-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. in view of Lindenthaler (US 6,361,494).

With regard to claim 4, Cho et al. do not disclose detecting muscle conditions. Lindenthaler teaches detecting muscle conditions associated with sleep apnea (Col. 1: 60 - Col. 2: 6). Lindenthaler teach that muscle conditions are an important factor in causing sleep apnea (Col. 1: 15-30). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Lindenthaler into the invention of

Cho et al. in order to provide a method in which muscular conditions are detected, along with other factors, to treat patients with sleep apnea.

With regard to claim 47, Cho et al. disclose detecting conditions associated with sleep quality of a patient, collecting sleep quality data based on the detected conditions, and evaluating, at least in part implantably, the sleep quality of a patient, as described above. Cho et al. do not disclose detecting the conditions while the patient is in a period of wakefulness. Lindenthaler teaches measuring muscle activity in the pharyngeal airways and sleep apnea while the subject is awake. Lindenthaler teaches that this is convenient, and increases availability of testing to patients (Col. 1: 60-65). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Lindenthaler into the invention of Cho et al. in order to provide the aforementioned advantages.

With regard to claim 48, Cho et al. disclose detecting physiological conditions associated with sleep quality (Col. 4: 29-33).

With regard to claim 49, and the limitation of detecting non-physiological conditions, Cho et al. disclose measuring the sleep time of the patient (Col. 9: 9-19).

With regard to claim 51, and the limitation of detecting a cardiovascular system condition, Cho et al. disclose detecting hypertension (Col. 8: 20-38).

With regard to claim 52, and the limitation wherein detecting conditions comprises detecting patient activity, Cho et al. disclose detecting limb movement (Col. 6: 53-65). With regard to the limitation of collecting data during the period of

wakefulness, Cho et al. disclose updating data when a patient has experienced a wake event (Block 650 in Fig. 6; Col. 11: 10-22).

With regard to claim 53, Cho et al. disclose storing the sleep quality data (Col. 5: 35-38).

With regard to claim 54, Cho et al. disclose transmitting the sleep data (Col. 8: 39-45).

With regard to claim 55, and the limitation wherein evaluating the sleep quality comprises determining one or more metrics associated with sleep quality, Cho et al. disclose gathering metrics associated with sleep apnea (Col. 3-24-38).

With regard to claim 56, Cho et al. disclose transmitting sleep quality data and the sleep quality evaluation to a separate device (Col. 8: 39-45).

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. in view of Kallok et al. (US 5,146,918). Cho et al. do not disclose detecting a nervous system condition. Kallok et al. teach detecting central nervous system inspiratory drive to the respiratory muscles to detect apnea. Kallok et al. that lack of nerve activity can be an indicator of apnea (Col. 2: 4-24). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Kallok et al. into the invention of Cho et al. in order to provide a system in which nervous system conditions are monitored to detect sleep apnea.

6. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. in view of Lindenthaler (US 6,361,494), as applied above, and further in view of Kallok

et al. (US 5,146,918). Cho et al., as modified by Lindenthaler, do not disclose detecting a nervous system condition. Kallok et al. teach detecting central nervous system inspiratory drive to the respiratory muscles to detect apnea. Kallok et al. teaches that lack of nerve activity can be an indicator of apnea (Col. 2: 4-24). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Kallok et al. into the invention of Cho et al., as modified by Lindenthaler, in order to provide a system in which nervous system conditions are monitored to detect sleep apnea.

7. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. in view of Steinschneider (US 6,059,725). Cho et al. do not disclose detecting an environmental or contextual condition. Steinschneider teaches that environmental conditions, such as ambient temperature and noise level, should be controlled when determining the probability of an episode of apnea (Col. 5: 16-19, 43-45; See also claim 1 and 2). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Steinschneider into the invention of Cho et al. in order to provide a system in which environmental conditions are monitored when diagnosing sleep apnea.

Response to Arguments

8. Applicant's arguments with respect to claims 4, 6-8, and 50 have been considered but are moot in view of the new ground(s) of rejection.

9. In response to applicant's argument that Cho does not teach or suggest the detection of non-physiological conditions, the examiner respectfully disagrees. Cho et al. disclose measuring the sleep time of the patient (Col. 9: 9-19). The applicant has listed sleep time as a non-physiological condition in Table 2, on page 6 of the specification. Therefore, the examiner asserts that the reference reads on the claims.

10. In response to applicant's argument that there is no suggestion to combine the references of Cho and Lindenthaler, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Cho and Lindenthaler disclose methods for detecting symptoms of sleep apnea. The method of Cho comprises detecting numerous physiological conditions, but does not include the specific feature of detecting muscle conditions. Lindenthaler teaches a method of detecting sleep apnea in wakeful patients, including measuring muscle conditions. Lindenthaler teaches the importance of muscle tone in the throat in relation to sleep apnea (Col. 1: 15-30). Obviousness requires only a reasonable expectation of success (See MPEP 2143.02). Since Cho discloses a method of detecting sleep apnea, and since Lindenthaler teaches that measurement of muscle tone in the throat is important

in detecting sleep apnea, it would be reasonable to expect success by incorporating Lindenthaler's teaching into Cho's method of detecting sleep apnea.

11. In response to the applicant's argument that the approach taught by Lindenthaler is not implantable, and would thus render the system of Cho unsatisfactory for its intended purpose, the examiner respectfully disagrees. The invention of Cho is a method used to detect and treat sleep apnea (Col. 1: 13-15). The implantable apparatus of Cho is used in the implementation of the method. For a method of detecting sleep apnea, the examiner asserts that it would be obvious to include a feature, which has been taught to be important in the detection of sleep apnea. Lindenthaler teaches that the feature of detecting muscle condition is important in the detection of sleep apnea. The examiner asserts that there is strong motivation to combine the teachings of Lindenthaler into the invention of Cho in order to produce a more comprehensive method of detecting sleep apnea.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joshua D. Crabtree whose telephone number is 571-272-8962. The examiner can normally be reached on 8:00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P. Olszewski can be reached on (571) 272-6788. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC
Joshua D. Crabtree
July 28, 2006

KATHLEEN MOSSER
PRIMARY EXAMINER